REMARKS

Claims 5, 9, 11-14, and 30 will be pending before the Examiner upon entry of the above amendments. Claim 10 has been canceled, and claims 5, 9 and 11 have been amended. Supports for the amendments to the claims can be found in the specification. For example, support for the amendment to claim 5 can be found, *e.g.*, at page 322, line 15, to page 323, line 6, and page 329, lines 5-11; support for the amendment to claim 9 can be found, *e.g.*, at page 135, line 9, to page 136, line 10; and support for the amendment to claim 11 can be found, *e.g.*, at page 314, lines 3-4. No new matter has been introduced.

The paragraph related to priority information (first paragraph on page 1) has been amended, upon the Examiner's request, to recite "claims the benefit of ..." instead of stating "claims priority to..." the priority applications.

A. Rejection Under 35 U.S.C. §§ 101, and 112 First Paragraph, Should Be Withdrawn

Claims 5, 9-14 and 30 are rejected under 35 U.S.C. § 101 for lacking a "patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility." See Office Action, the paragraph bridging pages 3 and 4.

Claims 5, 9-14 and 30 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, according to the Examiner, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, a skilled artisan would not know how to use the claimed invention.

Applicants respectfully submit that the instant specification teaches that the claimed nucleic acids can be used, *inter alia*, to differentiate certain cancer tissues from their corresponding normal tissues, *e.g.*, certain kidney cancer tissue from normal kidney tissue, and certain prostate cancer tissue from normal prostate tissue. The instant specification at, *e.g.*, page 376, line 10, to page 377, line 27, teaches how to detect the claimed nucleic acids in a biological sample. The instant specification further teaches, *e.g.*, at pages 510-512, Table LH, Panel 2D, that a nucleic acid molecule comprising SEQ ID NO: 53 is highly expressed in certain kidney cancer tissue as compared to normal kidney tissue, and such nucleic acid molecule is also highly expressed in certain prostate cancer tissue as compared to normal

prostate tissue. Therefore, the specification clearly teaches the use of the claimed nucleic acids for differentiating certain cancer tissues, *e.g.*, certain kidney cancer tissue or certain prostate cancer tissue, from their corresponding normal tissue, *e.g.*, normal kidney tissue or normal prostate tissue, of which use is specific, substantial and credible.

Applicants respectfully submit that the specificity of the expression data discussed above is not affected by the concern, as the Examiner states in the office action, that "the specification does not disclose whether any of the probes is specific for SEQ ID NO: 53 (see pp. 503-504) and all of the results are directed to expression of SEQ ID NO: 45 (pp. 517-519)." See Office Action, the paragraph bridging pages 4-5. Although the probes are not designed specifically for SEQ ID NO: 53, they are designed specifically for NOV15 (collectively termed CG56449). See specification at, *e.g.*, page 391, last paragraph. Different members in NOV15 share a high sequence homology. Thus, the data demonstrate the expression of NOV15 (including SEQ ID NO: 53) when the primers are designed within the homology region. As indicated on page 503, lines 15-20, of the instant specification, only the primer/probe set Aga422 does not correspond to SEQ ID NO: 53 (CG56449-08) (the alignment of the primer/probe sets to each member of CG56449 may also be verified by sequence alignment - a well-known technique in the art). The Examiner further states that "it is noted that these results are quite different from those of SEQ ID NO: 43 (p. 503), which also a NOV15 protein." Applicants respectfully submit that page 503 of instant specification does not contain such results as the Examiner alleges (SEQ ID NO: 43 represents CG56449-01). In another word, page 503 does not contain any data that indicate CG56449-01 is expressed differently from that of CG56449-08 (SEQ ID NO: 53).

Finally, with respect to the Examiner's statement that "there is no clear pattern of tissue expression, developmental expression, or correlation with disease tissue. SEQ ID NO: 45 is found in a plethora of tissues and at moderate levels in both normal and cancer cells" (see Office Action, page 5, lines 4-6), it is Applicants' position that the specification clearly teaches an expression correlation with certain cancer tissues (*e.g.*, kidney cancer tissue or prostate cancer tissue) as discussed above. It is irrelevant whether NOV15 is expressed in other normal tissues, as long as the specification teaches that NOV15 is differentially expressed in certain cancer tissues (*e.g.*, kidney cancer tissue or prostate cancer tissue) and their corresponding normal tissues (*e.g.*, normal kidney tissue or normal prostate tissue).

The Examiner's attention is further invited to the case law and M.P.E.P., which state that Applicants only need to assert one specific, substantial and credible utility of the claimed invention:

> It is common and sensible for an applicant to identify several specific utilities for an invention, particularly where the invention is a product (*e.g.*, a machine, an article of manufacture or a composition of matter). However, regardless of the category of invention that is claimed (*e.g.*, product or process), an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112; additional statements of utility, even if not "credible," do not render the claimed invention lacking in utility.

M.P.E.P. § 2107.02, I (Eighth Edition, August 2001, revised May 2004). Since the instant specification teaches a specific, substantial and credible utility, *i.e.*, to differentiate certain cancer tissues (*e.g.*, kidney cancer tissue or prostate cancer tissue) from their corresponding normal tissues (*e.g.*, normal kidney tissue or normal prostate tissue), the rejection under 37 U.S.C. § 101 should be withdrawn.

Claims 5, 9-14 and 30 are also rejected under 35 U.S.C. § 112, first paragraph, for not being supported by either a specific and substantial asserted utility or a well established utility. Applicants have demonstrated above that claims 5, 9, 11-14 and 30 (claim 10 has been canceled) are supported by a specific, substantial, and credible utility. Therefore, this rejection should be withdrawn.

B. Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement, Should be Withdrawn

Claim 30 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. In particular, the Examiner states that while it is well known in the art how to make and administer a composition comprising a nucleic acid and a pharmaceutically acceptable carrier, and the specification discloses how to do so, "one skilled in the art would not know how to use the invention, *i.e.*, what to treat, with the inventive composition." See Office Action, page 9, lines 4-5.

As discussed in Section A above, Applicants have demonstrated the claimed nucleic acid molecules can be used to differentiate certain cancer tissues, such as certain kidney cancer tissues or certain prostate cancer tissues, from their corresponding normal tissues, *e.g.*,

normal kidney tissue or normal prostate tissue. As such, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

C. Rejection Under 35 U.S.C. §112, Second Paragraph, Should Be Withdrawn

Claims 10-11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Examiner rejected (1) claim 10 for directing to a nucleic acid hybridizing under "stringent conditions" to SEQ ID NO: 53, where it is unclear what Applicants intend for "stringent" hybridization conditions; and (2) claim 11 for reciting the term "complement," which, according to the Examiner, may have many meanings in the art and it is unclear what meaning Applicants intend for.

Claim 10 has been canceled, thus, the rejection to claim 10 is moot and should be withdrawn.

Claim 11, as amended, clearly indicates that the claimed nucleic acids comprise a sequence that is complementary to the full length of the nucleic acid sequences as claimed in claim 5. Thus, Applicants respectfully request that this rejection be withdrawn.

D. Rejection Under 35 U.S.C. §102 Should Be Withdrawn

Claims 10-11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Nakayama *et al.* (NCBI accession number AB011532) ("Nakayama"), as being supported by Meinkoth *et al.*, Analytical Biochem. (1984) 138:267-284 ("Meinkoth"). In particular, the Examiner states that using the equation set forth on page 269 of Meinkoth and the hybridization conditions set forth in the instant specification on page 319, the sequence disclosed in Nakayama would be expected to hybridize to SEQ ID NO: 53.

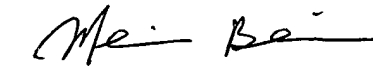
Claim 10 has been canceled, and claim 11 has been amended to clearly indicate that the claimed nucleic acids comprises a sequence that is complementary to the full length of the nucleic acid sequences as claimed in claim 5 – which is not taught by either Nakayama or Meinkoth. As such, Nakayam and Meinkoth do not anticipate the claimed invention, and the rejection under 35 U.S.C. § 102 should be withdrawn.

CONCLUSION

Applicants respectfully request that the amendments and remarks made herein be entered and made of record in the file history of the present application. Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

Date: January 10, 2004



45,470

Mei L. Benni (Reg. No.)

CuraGen Corporation
555 Long Wharf Drive
New Haven, CT 06511
Tel: (203) 974-6306